

### **REMARKS**

These remarks are responsive to the Office Action mailed on March 22, 2010 (“the Office Action”). The Applicant thanks the Examiner for the examination of the above-referenced Application.

#### **Status of the Claims**

At the time of the Office Action, claims 1-4, 6-8, 10, 11, 13-59, and 61-68 were pending, with claims 16-54 being withdrawn from consideration, claims 1-4, 6-8, 10, 11, 13, 14, 55-59, and 61-68 being rejected, and claim 15 being objected to. Claims 4, 8, 10, 11, 13-15, 55-59, 62-66, and 68 are amended herein. Support for the amendments herein can be found throughout the specification, the figures, and the claims themselves. For example, support may be found in Figures 44-58. No new matter is being submitted.

#### **Claim Objections**

Claims 4 and 11 are objected to because of an alleged informality. Office Action, p. 2. Amendments to claims 4 and 11 are made herein that address the alleged informality. Accordingly, Applicant hereby requests that these claim objections be withdrawn.

#### **35 U.S.C. § 112 Rejections**

Claims 4, 10, 11, 13-15, 55-59, and 61-67 currently stand rejected under 35 U.S.C. § 112, first paragraph, for allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention. Office Action, p. 2.

Amendments to claims 4 and 11 are made herein that remove the allegedly indefinite language.

An amendment to claim 10 is made herein to change the term “distal” to “proximal.” The amendment addresses the alleged indefiniteness of claim 10.

Amendments to claims 55 and 62 are made herein that remove the allegedly indefinite language, while still maintaining language that makes it clear that the claimed extension member actually protrudes from the lower cap.

Since the amendments to claims 4, 10, 11, 55, and 62 obviate all of the rejections under 35 U.S.C. § 112, second paragraph, the Applicant respectfully requests that the rejections be withdrawn.

**35 U.S.C. § 103 Rejections**

Pending claims 1-4, 10, 11, 55-59, and 61-68 currently stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Barker (U.S. Patent No. 6,660,004), in view of Vienney (WO 03/024343; Citations herein are to U.S. Patent Application Publication No. 2005/0240180, the translated national stage entry of Vienney) and further in view of Puno (U.S. Patent No. 5,360,431). Office Action, p. 4. In order to render a claim obvious, a combination of references must teach or suggest each and every claim limitation. The Applicant respectfully submits that the cited references, alone or combined, fail to render the present invention obvious.

With respect to independent claims 1, 55, 62, and 68, the Examiner contends that Vienney teaches an upper cap having an opening with a second profile that receives a post with a first profile and that the first and second profiles are geometrically similar. In particular, the Examiner states that Vienney teaches “an inner cavity having a second profile passing through the upper cap from an upper surface to a lower surface that

includes an opening to receive a post (33) having a first profile that is geometrically similar to the second profile.” Office Action, p. 5.

The Applicant respectfully submits that Vienney fails to teach or render obvious various features of the independent claims related to the post and/or the opening. In particular, Vienney fails to teach or suggest “an upper cap and a lower cap joined by a post...said upper cap...comprises an opening to receive said post; and...wherein said post is provided with an outer perimeter with a first profile and said opening is provided with a second profile that is geometrically similar,” as recited by claim 1; fails to teach or render obvious a “second end [of said lower cap] having a post, said post having an outer perimeter with a first profile...an opening through said first end and said second end [of said upper cap]...said opening having an interior surface forming a second profile...wherein said first profile and said second profile are geometrically similar” as recited by claim 55; fails to teach or render obvious “said lower cap having a first end, and a second end, said second end having a post protruding therefrom” as recited in claim 62; and fails to teach or render obvious “said second end [of said lower cap] is provided with a second orientation means for providing proper orientation between said lower cap and said upper cap, said second orientation means having an uninterrupted periphery” as recited in amended claim 68.

Claims 1, 55, and 62 each positively recite a “post.” In contrast to and instead of a post, Vienney discloses a series of lugs (33). Vienney, ¶¶ 0039-0040; Figures 4 – 7. Vienney’s series of lugs do not teach or render obvious a **post** as positively recited in claims 1, 55, and 62. Moreover, Vienney’s series of lugs do not anticipate a **post** provided with an **outer perimeter with a first profile** as positively recited in claims 1

and 55 nor do they teach or render obvious an orientation means having an **uninterrupted periphery** as positively recited in claim 68.

Additionally, Vienney fails to teach geometrically similar first and second profiles as recited in claims 1 and 55. The term “geometrically similar” recited in claim 1 and 55 is defined as “having the same shape: differing only in size and position – used of geometrical figures” Webster’s Third New Int’l Dictionary p. 2120 (1981). Whatever profile Vienney’s lugs do provide, Vienney fails to disclose an opening with a profile that is *geometrically similar* as positively recited in claims 1 and 55.

Therefore, Vienney fails to teach the aforementioned claim features that are positively recited in claims 1, 55, 62, and 68. The remaining references relied on in the 35 U.S.C. § 103(a) rejection of those claims also fail to teach or suggest such claim features.

With respect to independent claim 1, the Examiner contends that Barker teaches a locking assembly that locks a rod **in contact with** the proximal end of a bone screw as recited in independent claim 1. In particular, the Examiner states that Barker teaches the “locking assembly locks the rod to the housing in contact with the proximal end of the bone screw.” Office Action p. 4. The Examiner also states that Barker teaches that “a driving instrument is inserted into the cavity of the locking assembly and rotates the locking assembly thereby engaging at least a portion of a male thread with the female threads of the housing causing the locking assembly to translate longitudinally into the housing and in contact with the rod, which forces the rod into a locked relationship with the proximal end of a bone screw.” Office Action pp. 4-5.

However, Barker does not teach that the locking assembly locks the rod **in contact** with the proximal end of the bone screw. Rather, Barker explicitly teaches that a crown member 70 is interposed between elongated member R and the head 54 of the bone anchor 50. *See e.g.*, Barker FIG. 7 and Barker Col. 8, lines 27-31 (“As compression member 120 is tightened, elongated member R is forced downward against crown member 70, which pushes crown member 70 down onto head 54 of bone anchor 50.”). The remaining references relied on in the 35 U.S.C. § 103(a) rejection also fail to teach or suggest that the locking assembly locks a rod **in contact with** the proximal end of a bone screw. For example, in Vienney there is not a separate bone anchor and housing. Rather, the two arms 11 and 12 are monolithic with the anchoring member 1 of Vienney. *See e.g.*, Vienney FIG. 1 and FIG. 2 and ¶ 0036 (“The anchoring member 1 has a head comprising two arms 11 and 12 extending opposite each other in order to form a U-shaped opening 12.”). Moreover, the proximal end of the anchoring member 1 in Vienney is atop the arms 10 and 11 of the anchoring member 1 and clearly not in contact with the linking member 2. *Id.* Accordingly, Vienney does not teach a rod in contact with the **proximal end** of a bone screw. Also, for example, Puno states that the “rod 18 is grasped in the tunnel 84 formed between the rod-receiving channel 54 of the anchor seat 23 and the arch 72 of the cap 25.” Puno Col. 6, lines 24-26.

Accordingly, the combination of references relied upon in the 35 U.S.C. § 103(a) rejection of claim 1 fail to teach or suggest the feature of claim 1 that the locking assembly locks a rod **in contact with** the proximal end of a bone screw.

Also, with respect to independent claims 1, 55, 62, and 68, the Applicant respectfully submits that the Office Action fails to properly address the pertinent “Timing

Structure” features of those claims. In particular, the Office Action fails to address the “wherein said threads on said upper cap and said threads in said flanges further comprise at least one start thread timed to properly engage each other when said extension is located within said channel” feature of claim 1; fails to address the “wherein only one orientation of said second profile relative to said first profile allows said upper cap to be received in said housing” feature of claim 55; fails to address the “wherein one or two orientations of said upper opening relative to said extension member allows said upper cap to be axially received in said housing” feature of claim 62; and fails to address the “wherein when said first orientation means is properly oriented with respect to said housing and said upper cap opening is properly oriented with respect to said second orientation means, said male threads will align with said female threads to prevent cross threading” feature of claim 68.

The Examiner contends that Puno discloses a device that teaches the Timing Structure features of the independent claims. Office Action, p. 6. However, in the device of Puno, the alleged upper cap (nut 27) and the alleged lower cap (cap 25) are not joined to one another and therefore are not timed with respect to one another as variously claimed in the pending independent claims.

For example, with respect to independent claim 1, Puno does not teach or suggest threads on an upper cap and threads in flanges that each have at least one start thread **timed** to properly engage each other **when said extension member is located within said channel**. Rather, the nut 27 of Puno may be remote (*e.g.*, still in a surgeon’s hand) from the threaded area 76 when the cap 25 is located within a channel. Moreover, when the nut 27 is positioned by the surgeon for placement about the thread 76, it will not

necessarily be **timed** to appropriately engage a start thread of the threaded area 76.

Rather, the surgeon may have to tinker with the rotational positioning of the nut 27 in order to properly locate a start thread or may accidentally cross-thread the nut 27.

Similarly, with respect to independent claim 68, Puno does not teach or suggest male threads on an upper cap that will align with female threads when a first orientation means is properly oriented with respect to a housing and an upper cap opening is properly oriented with respect to second orientation means. When the nut 27 of Puno is positioned by the surgeon for placement about the male threaded area 76, it will not necessarily be **aligned** with female threaded area 76. Rather, the surgeon may have to tinker with the rotational positioning of the nut 27 in order to properly align it with the female thread.

Also, for example, with respect to independent claim 55, Puno does not teach or suggest that no more than two orientations of a second profile (of the opening) relative to a first profile (of the post) allows the upper cap to be received in the housing. Even ignoring the fact that Puno does not teach a post or an opening as claimed, the cap 25 and the nut 27 thereof may be placed in four distinct orientations relative to one another (not the claimed “no more than **two**”). In particular, the cap 25 of Puno may be independently placed at two unique orientations. Moreover, the nut 27 may be threaded onto the thread 76 independently of the cap 25 in at least two independent orientations (with a first side of the nut 27 first threaded onto the male threads 76 first as shown in FIG. 4 of Puno or by flipping the nut 27 and first threading a second side of the nut 27 onto the male threads 76). Accordingly, the nut 27 and the cap 25 of Puno may be placed at least in four unique orientations relative to one another, which is more than the “no more than two” recited in claim 55.

Also, for example, with respect to independent claim 62, Puno similarly fails to teach or suggest that one or two orientations of an upper opening relative to the extension member allows the upper cap to be axially received in the housing. Again, the nut 27 and the cap 25 (to which the alleged extensions of Puno are attached) of Puno may be placed at least in four unique orientations relative to one another, which is more than the “one or two” recited in claim 62.

The remaining references relied on in the 35 U.S.C. § 103(a) rejection of the independent claims likewise fail to teach or suggest the Timing Structure aspects of the independent claims.

For at least the reasons set forth herein, the Applicants respectfully submit that the cited reference fails to anticipate independent claims 1, 55, 62, and 68, and any claim depending therefrom. Thus, the Applicants respectfully request that this rejection be withdrawn.

With respect to amended dependent claims 4, 8, and 11 the Applicant respectively submits that the cited combination of references fail to teach or suggest an extension that is dimensioned to “**only reside within said channel**” as recited in those amended claims. The Examiner contends that the clamping flanges 46/47 of Puno constitute an integral extension that protrudes from the lower cap and that they include an extension of the semi-cylindrical surface of the lower cap. Office Action, p. 6. However, as clearly shown in various Figures of Puno, the clamping flanges 46/47 extend outside of the channel 51/52 of Puno. *See e.g.*, Puno FIG. 5 and FIG. 6. In fact, the clamping flanges 46/47 must extend outside of the channel of Puno in order to accomplish their function of cooperating with the nut 27 as it is tightened about the **exterior** of the anchor seat. Puno



Col. 6, lines 21-23 (“As the nut 27 is rotated about the anchor seat 25, it cooperates with the top side of the flange 46, 47 to tighten the clamp 25 in relation to the rod support 23.”). Accordingly, the clamping flanges 46/47 of Puno must extend outside of the channel and fail to teach or suggest an extension that is dimensioned to “only reside within said channel” as recited in amended dependent claims 4, 8, and 11.

With respect to dependent claims 56-59 and 63-66, the Applicant respectively submits that the cited combination of references fail to teach or suggest the features of the post recited in claims 55 and 62 and likewise fail to teach the additional features of the post recited in claims 56-59 and 63-66. The Applicants have amended claims 56-59 and 63-66 to further clarify which axis or plane the post is symmetric or asymmetric about.

Dependent claims 13 and 14 currently stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Barker (U.S. Patent No. 6,660,004), in view of Vienney (WO 03/024343), further in view of Puno (U.S. Patent No. 5,360,431), further in view of Katz (U.S. Patent No. 5,989,254).

The Applicants respectively submit that the cited combination of references fails to teach or suggest a **depression** as recited in dependent claim 13 and fails to teach or suggest a **fixed** apurtenance as recited in amended dependent claim 14.

Claim 13 recites a **depression**. In contrast, Katz teaches a **hole** extending completely through a portion of the head 3 of the screw. Katz, FIG. 1; Col. 2, lines 61-65 (“To assist in inserting the screw into the appropriate bone in use, the coupling member (6) is retained on the screw head (3) by means of a pin (14) inserted through a radial hole in the coupling member (6) into the head (3) to be retained by frictional engagement.”). Applicants have amended claim 14 herein to add the feature that the apurtenance

projecting radially inward from the flanges is **fixed**. In contrast, Katz teaches a **separate non-fixed** pin (14) that may be inserted through an opening in coupling member 6. Katz, FIG. 6; Col. 2, lines 61-65. Given the failures of Katz to teach these features of claims 13 and 14, the Applicant respectfully requests that this rejection be withdrawn.

Moreover, the Examiner has failed to establish a *prima facie* case of obviousness of claims 1-4, 10, 11, 55-59, and 61-68 since the Office Action does not articulate a clear basis for combining Barker and Vienney and does not articulate a clear basis for combining Barker and Vienney with Puno. *See* MPEP § 2143 (*e.g.*, “The key to supporting any rejection under 35 U.S.C. 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious.”)

In particular, with respect to the Barker and Vienney combination, the Examiner has mischaracterized the teachings thereof in suggesting that they both teach “devices including locking assemblies positioned within a housing to force a rod into a locked relationship **with the housing**.” Office action pp. 5-6 (emphasis added). Accordingly, the Examiner’s finding that one of ordinary skill in the art would have substituted the locking assembly of Barker for the locking assembly of Vienney “in order to achieve the predictable results of forcing a rod into a locked relationship **with the housing**” is not proper to support a *prima facie* case of obviousness.

MPEP § 2143 provides a number of bases under which, when properly articulated, an examiner may properly establish a *prima facie* case of obviousness. One such basis, which the Examiner appears to have relied upon in combining Barker and Vienney, is the “Use of Known Technique to Improve Similar Devices (Methods, or Products) in the Same Way.” MPEP § 2143, Section C. To properly reject a claim under

such a rationale the MPEP requires, *inter alia*, “a finding that one of ordinary skill in the art could have applied the known ‘improvement’ technique in the same way to the ‘base’ device (method, or product) and the results would have been predictable to one of ordinary skill in the art.” The Examiner contends that the predictable results of combining Barker and Vienney is “forcing a rod into a locked relationship with the housing.” Office Action, p. 6.

However, neither Barker nor Vienney teaches the forcing of a rod into a locked relationship with a **housing** and, accordingly, combination of the two references would not achieve the result of forcing a rod into a locked relationship with a housing. Barker teaches that the elongated member R thereof is locked between a crown member 70 and a compression member 120 and does not teach or suggest that it is forced into a locked relationship with a **housing** as contended by the Examiner. *See e.g.*, Barker FIG. 7 and Barker Col. 8, lines 27-31 (“As compression member 120 is tightened, elongated member R is forced downward against crown member 70, which pushes crown member 70 down onto head 54 of bone anchor 50.”). Moreover, Vienney does not even teach a housing. Rather, Vienney teaches a bone anchor 1 having a monolithically formed head. In Vienney, the connecting member 2 is inserted into an opening 12 formed between two arms 11 and 12 of the **anchoring member 1** and will be tightened into contact with the **anchoring member 1**. *See e.g.*, Vienney FIG. 1 and FIG. 2 and ¶ 0036.

In light of the teachings of Barker and Vienney, the Examiner’s stated reasoning for combining the references is illogical. Accordingly, the Office Action does not articulate a clear basis for combining the references, which is required by the MPEP in

order to establish a *prima facie* case of obviousness. Thus, the Applicant respectfully requests that this rejection be withdrawn.

Moreover, even if one of ordinary skill in the art had an objective reason to combine Barker and Vienney, they would not then look to Puno “in order to help align the lower cap relative to the rod” as suggested by the Examiner. Office Action, p. 6. Such a suggestion is insufficient to establish a *prima facie* case of obviousness since it provides no clearly articulated reasoning why one of ordinary skill in the art would **combine** the teachings of the references. *See e.g.*, MPEP § 2143.

One of ordinary skill in the art would not have combined the teachings of Barker and Vienney with Puno “in order to help align the lower cap relative to the rod,” since the proposed combination of Barker and Vienney would already provide structure to keep the lower cap in proper alignment with the rod. Namely, incorporating the substantially rectangular lower cap (3) of Vienney into the device of Barker would require the lower cap (3) to be properly longitudinally aligned in the channel of Barker. As a result, one of ordinary skill in the art would have no motivation to look to Puno for structure to help align the lower cap relative to the rod since the rectangular nature of the lower cap of Vienney already provides alignment functionality. Moreover, as previously discussed herein, the flanges 46/47 of Puno are provided for **clamping** functionality and not alignment purposes. Accordingly, one would not look to such structure of Puno to help align the lower cap as alleged by the Examiner.

The Examiner’s stated reasoning for combining the cited references is illogical in light of the teachings of the references and does not constitute an objective reason for combining the teachings of the references. As a result, a *prima facie* case of obviousness

has not been established and the Applicant therefore requests that this rejection be withdrawn.

Any 35 USC § 103 rejections of dependent claims not specifically argued herein are not acquiesced to by the Applicant. Such dependent claims are allowable at least since they depend from independent claims which are patentably distinct from the cited references.

**CONCLUSION**

The Applicant respectfully submits that the application is in condition for allowance, and reconsideration and notice of allowance are respectfully requested. If the Examiner believes that prosecution might be advanced by discussing the application with the Applicant's counsel, in person or over the telephone, the Applicant's counsel would welcome the opportunity to do so.

Respectfully submitted,

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